AF/1615

TRANSMITTAL LETTER (General - Patent Pending)	Docket No. 112703-35

In Re Application Of: **Ream et al.**

Serial No.	Filing Date	Examiner	Group Art Unit
09/286,818	April 6, 1999	S. Tran	1615

Title:

PHARMACEUTICAL CHEWING GUM FORMULATIONS

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith is:

Appellants' Reply Brief (3 pages) (triplicate); and
Return Receipt Postcard

in the above identified application.

- ☒ No additional fee is required.
- ☐ A check in the amount of is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **02-1818** as described below.
  - ☐ Charge the amount of
  - ☒ Credit any overpayment.
  - ☒ Charge any additional fee required.

Dated: **February 10, 2004**

Signature

Robert M. Barrett (30,142)
ATTORNEYS FOR APPLICANTS
Bell, Boyd & Lloyd LLC
P.O. Box 1135
Chicago, Illinois 60690-1135

I certify that this document and fee is being deposited on **2/10/2004** with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Signature of Person Mailing Correspondence

Renee Street

Typed or Printed Name of Person Mailing Correspondence

cc:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants:	Ream et al.
Appl. No.:	09/286,818
Conf. No.:	5472
Filed:	April 6, 1999
Title:	PHARMACEUTICAL CHEWING GUM FORMULATIONS
Art Unit:	1615
Examiner:	S. Tran
Docket No.:	112703-035

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to Examiner's Answer dated December 17, 2003.

II. THE EXAMINER'S ANSWER AS WELL AS THE REJECTIONS IGNORES ONE OF THE DISTINGUISHING CLAIM ELEMENTS

In order to craft a rejection, the Examiner has ignored one of the salient claimed elements. In this regard, Appellants' claimed invention, in part, relates to the ability to deliver a medicament or active agent orally. Indeed, the invention allows the oral delivery of a medicament utilizing less medicament than that typically administered to treat the applicable disorder.

Appellants' patent application is replete with the discussions as to the increased bioavailability of the medicament when it is delivered through the drug delivery system of Appellants' claimed invention. In fact, Appellants' patent application sets forth detailed examples of the delivery of caffeine utilizing the drug delivery system of the present invention. These examples demonstrate that less caffeine can be provided in the claimed product than that that is typically ingested, for example through No Doze, and still achieve as good if not greater

effect. Thus, Appellants are able to achieve a bioavailability utilizing an oral drug delivery system that approaches that of a parenteral administration.

This feature, as tacitly admitted by the Examiner's Answer, has not been considered. For example, the Examiner states "Again, the Examiner has not been able to compare 'less than a typical amount' or ordinary amount taught by [the references]." Thus, Appellants submit that the Examiner has admitted that this claimed element has been ignored by the Patent Office.

III. THE TERM "LESS THAN THE TYPICAL AMOUNT" IS CLEAR AND ENTITLED TO PATENTABLE WEIGHT

Of course, as set forth in Appellants' Appeal Brief, the caselaw is clear, the standard for determining whether or not a claim is definite is whether or not those skilled in the art would understand what is claimed when the claim is read in light of the specification. Further, an Applicant is only required to claim in as precise language as the subject matter permits. (See cases cited in Appellants' Appeal Brief).

Appellants have surprisingly found that, pursuant to the present invention, less active agent or medicament is required when using the drug delivery system of Appellants' claimed invention as opposed to the enteral administration of a similar drug. What is typically administered to achieve an effect or to treat a disorder is of course known to those skilled in the art. Otherwise, how could any product be dispensed to the public at large or a physician or other healthcare provider dispense any pharmaceutical compound. The literature is replete with documentation on what is typically or commonly administered to treat a disorder. Those skilled in the art readily know or can determine what this amount is. Appellants claimed invention is treating the same disorder or achieving the same effect with less than that amount.

Indeed, the Examiner's failure to consider this limitation under the guise that it is indefinite is belied by the references cited in posing the rejection. *Cherukuri*, the principal reference, states that the amount of medicament present is "the ordinary dosage required to obtain the desired result." How does one know what the ordinary dosage is? *Cherukuri* states "such dosages are known to the skilled practitioner in the medical arts." (See column 7, lines 18-21). The Patent Office has relied on *Cherukuri* as providing an enabling disclosure of a chewing gum including a medicament. Is the Patent Office suggesting that *Cherukuri's* statement that ordinary dosage is vague and indefinite and therefore *Cherukuri* does not provide an enabling disclosure? If so, how is *Cherukuri* relied upon in the rejection?

Appellants do not suggest that *Cherukuri* does not provide an enabling disclosure. Of course, it does. Much like Appellants' claimed invention, what is typically administered or ordinarily administered is well-known in the art.

The Examiner states that it is not possible to compare the terms "commonly" and "typically." Appellants note that these terms are synonyms. Appellants refer the Patent Office to Roget's Second The New Thesaurus. As set forth therein, "ordinary" is a synonym to "common" and "usual." Likewise, the synonym to "typical" is "common." Thus, these terms have substantially identical meaning. Thus, the Patent Office can readily compare these terms, if it makes it easier, Appellants respectfully request the Patent Office substitute commonly in both disclosures.

Thus, if anything, *Cherukuri* teaches away from the claimed invention. *Cherukuri* teaches you should use the common dosage; Appellants claim less than the common dosage.

The failure of the Patent Office to consider the limitation, that is specifically taught away from by the cited references, is in and of itself a basis for this Board to reverse the Examiner's rejection. Accordingly, Appellants respectfully request that the Patent Board of Appeals reverse the Examiner's rejection.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

Robert M. Barrett
Reg. No. 30,142
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4204

Dated: February 10, 2004